

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

**In re Novartis and Par Antitrust
Litigation**

CASE NO. 1:18-CV-04361-AKH

This Document Relates to:

All Actions

**DECLARATION OF ZAREMA A. JARAMILLO IN SUPPORT OF NON-PARTIES
LUPIN LTD. AND LUPIN PHARMACEUTICALS, INC.'S
OPPOSITION TO MOTION TO COMPEL**

I, Zarema A. Jaramillo, declare as follows:

1. I am an attorney duly authorized to practice law in the District of Columbia, the state of New York, and before the Southern District of New York. I am a Partner at Lowenstein Sandler LLP, counsel to Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, “Lupin”), a non-party recipient of a Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action (the “Subpoena”) issued by the Plaintiffs in *In re Novartis and Par Antitrust Litigation*, No. 1:18-cv-04361, pending in the Southern District of New York (the “Action”). I and attorneys under my supervision have been involved in the meet-and-confer discussions with Plaintiffs in the Action regarding the scope of the Subpoena, and Lupin’s productions in response thereto.

2. On December 18, 2018, Plaintiffs asked, and the next day, Lupin agreed to accept service of the Subpoena to Lupin Pharmaceuticals, Inc. The Subpoena, attached as Exhibit 1 to the *Declaration of Dan Chiorean* (“Chiorean Decl.”), (ECF No. 246), requested production of 22 categories of documents.

3. Pursuant to an agreement with Plaintiffs, Lupin responded and objected to the Subpoena on January 18, 2019. A true and correct copy of Lupin's Responses and Objections to the Subpoena is attached as Exhibit 4 to the Chiorean Declaration. In its Responses and Objections, Lupin stated, among other objections, that the Subpoena was overly broad, unduly burdensome, and disproportionate to the needs of the case. Lupin also agreed to produce Lupin's entire ANDA file for Generic Exforge as it is maintained in the ordinary course of business. Lupin further agreed to meet and confer with Plaintiffs concerning certain other requests in the Subpoena.

4. Accordingly, I reached out to Plaintiffs on January 22, 2019 to meet and confer regarding the scope of the Subpoena.

5. On February 4, 2019, I participated in the first telephonic meet and confer call with Plaintiffs' counsel, Dan Chiorean, to discuss the scope of the Subpoena.

6. On February 11, 2019, Plaintiffs withdrew the initial Subpoena to Lupin Pharmaceuticals, Inc. and served another Subpoena, directed to both to Lupin Ltd. and Lupin Pharmaceuticals, Inc., served on behalf of the Direct Purchaser Plaintiffs, the End-Payor Plaintiffs, and the Walgreen Plaintiffs. On February 18, 2019, Lupin accepted service of the revised Subpoena, and on February 25, 2019, Lupin responded and objected to the revised Subpoena.¹

¹ Separately, on January 2, 2019, Plaintiffs served a Subpoena on Novel Laboratories, Inc. ("Novel") via its registered agent for service of process in Delaware. On February 20, 2019, after learning of the Subpoena to Novel, we wrote to Plaintiffs, advising them that Novel had been acquired by Lupin in 2016, and thus we would be responding and objecting to that Subpoena on behalf of Novel as well. On February 22, 2019, Plaintiffs responded and noted that they had intended to file a motion to compel Novel to comply with the Subpoena, but would "hold off" "for the time being." A true and correct copy of this email exchange is annexed hereto as **Exhibit 1**. Novel served its Responses and Objections to the Subpoena on March 4, 2019. Although Plaintiffs have not moved to compel Novel's compliance with the Subpoena, Lupin includes reference to the subpoena to Novel herein for purposes of completing the record concerning Lupin's and Novel's efforts to comply with Plaintiffs' subpoenas.

7. The next meet and confers with Plaintiffs took place on March 11, 2019, and March 29, 2019. In advance of the meet and confer that took place on March 29, 2019, my associate, Katie Glynn, emailed Plaintiffs indicating that Lupin agreed to produce documents in response to eight of Plaintiffs' 22 requests. Lupin confirmed that it did not have documents responsive to four of the requests, and objected on the basis of burden to the remaining ten requests. Relevant to this Motion, Lupin agreed to produce "minutes from Lupin's New Product Launch meetings that discuss Generic Exforge or Generic Exforge HCT Launch plans" and "documents sufficient to show Lupin's ability to scale-up and launch Generic Exforge and Generic Exforge HCT, to the extent such documents are available."² (Chiorean Decl. Ex. 12.)

8. Plaintiffs responded to Lupin's offer by letter dated April 3, 2019. Plaintiffs accepted Lupin's offer with respect to three requests (1, 2 & 6), conditionally accepted Lupin's offer depending upon Lupin's agreement to produce documents within Plaintiffs' requested date range as to two requests (3, 7), made a counterproposal with respect to ten requests (4, 5, 8, 9, 10, 11, 14, 15, 16 and 22).³ (Chiorean Decl. Ex. 13.)

9. Lupin responded in a letter dated April 19, 2019, confirming that the parties had reached agreement as to twelve requests and requested that Plaintiffs articulate their basis for seeking production in response to six other remaining requests. Relevant to this Motion, Lupin agreed in the April 19th letter to produce "its entire ANDA file for generic Exforge and generic Exforge HCT, as those files are maintained in the ordinary course of business." In response to Plaintiffs' refusal to accept Lupin's March 29th offer regarding launch and manufacturing documents, Lupin inquired whether Plaintiffs would agree to cost shifting as to these two

² We further indicated that Novel would be willing to produce documents in response to two requests, because Novel develops, but does not market or sell generic pharmaceuticals. (Chiorean Decl. Ex. 12.)

³ With respect to Novel, Plaintiff reiterated the same positions. (Chiorean Decl. Ex. 13.)

categories of documents. Plaintiffs never responded to Lupin's inquiry regarding cost shifting. (Chiorean Decl. Ex. 2.)

10. On June 26, 2019, Lupin made its initial production in response to the subpoena, of 410 documents (11,187 pages) consisting of Lupin's ANDA file for generic Exforge as it was maintained in the ordinary course of business, as well as its Paragraph IV Certification Notice letters to Novartis related to generic Exforge and generic Exforge HCT.⁴ A true and correct copy of the letter accompanying Lupin's first production is annexed hereto as **Exhibit 2**.

11. On June 14, 2019, Lupin made a supplemental production of six documents (six pages) consisting of Lupin organizational charts. (Chiorean Decl. Ex. 6.)⁵

12. On July 22, 2019, Plaintiffs demanded that Lupin (and Novel) complete their productions by August 5, 2019, or Plaintiffs would "be forced to seek redress from the court." A true and correct copy of Plaintiffs' July 22, 2019 email to Lupin is annexed hereto as **Exhibit 3**.

13. On August 5, 2019 Lupin served a supplemental production of ten documents (237 pages) consisting of process validation information for generic Exforge and generic Exforge HCT and Lupin's transactional data regarding the same products.⁶ (Chiorean Decl. Ex. 8.)

14. On August 13, 2019, Plaintiffs wrote to Lupin raising questions concerning Lupin's (and Novel's) production of transactional data and demanding a response by August 23, 2019. A true and correct copy of Plaintiffs' August 13, 2019 letter to Lupin is annexed hereto as **Exhibit 4**.

⁴ On June 26, 2019, Novel made its initial production of 837 documents (18,067 pages), consisting of Novel's ANDA file for generic Exforge as it was maintained in the ordinary course of business, as well as its Paragraph IV Certification Notice letters to Novartis related to generic Exforge and generic Exforge HCT. A true and correct copy of the letter accompanying Novel's June 26, 2019 is annexed hereto as **Exhibit 5**.

⁵ On June 27, 2019 and July 11, 2019, Plaintiffs sought clarification whether Novel had "agreed to produce the same categories of documents responsive to Plaintiffs' subpoena that Lupin agreed to produce." On July 16, 2019, Lupin confirmed Novel's agreement to "produce the same categories of documents that Lupin agreed to produce, provided that such documents are within its possession, custody or control." (Chiorean Decl. Ex. 7)

⁶ That same day, Novel served a supplemental production of 1 document, reflecting Novel's transactional data. A true and correct copy of the letter accompanying Novel's August 5, 2019 production is annexed hereto as **Exhibit 6**.

15. Plaintiffs again wrote to Lupin on August 22, 2019, demanding that Lupin and Novel complete their productions by September 3, 2019, and threatening to move to compel. A true and correct copy of Plaintiffs' August 22, 2019 email to Lupin is annexed hereto as **Exhibit 7**.

16. On September 2, 2019, Lupin responded to Plaintiffs, stating that Lupin (and Novel) had not located any additional responsive documents, but that its reasonable search was continuing, and that any responsive documents identified would be produced. Lupin noted that "the documents produced so far show when the companies received FDA approval, when they began marketing generic Exforge, and how much generic Exforge they have sold since launch" and asked Plaintiffs to "explain what additional information belonging to these third-parties is necessary for Plaintiffs to continue litigating their antitrust case against Par and Novartis." A true and correct copy of Lupin's September 2, 2019 email to Plaintiffs is annexed hereto as **Exhibit 8**.

17. Plaintiffs responded on September 25, 2019, demanding that Lupin and Novel complete their productions by October 9, 2019, and again threatening to move to compel. Plaintiffs failed to address the question raised in Lupin's September 2, 2019 letter. (Chiorean Decl., Ex. 9.)

18. On October 8, 2019, Lupin responded to Plaintiffs, noting that Plaintiffs had failed to address Lupin's questions about the need for further document productions. Nevertheless, Lupin made a supplemental production of 661 documents (8,619 pages) pursuant to an "agreement between Lupin and Plaintiffs regarding the narrowed scope of the document requests in the Lupin Subpoena." Lupin's production consisted of additional ANDA files and manufacturing documents. Lupin's letter noted further that Novel was still responding to the

FDA's inquiries in the ANDA review cycle into January 2015, two months before the FDA approved Novel's ANDA for generic Exforge. Therefore, "Novel launched immediately upon FDA approval of its ANDA."⁷ (Chiorean Decl., Ex. 10.)

19. Plaintiffs did not respond to Lupin's October 8, 2019 letter, although Plaintiffs inquired with us several times in the fall of 2019 about a response to their August 13, 2019 letter asking questions about Lupin's transactional data.

20. More than three months later, on January 13, 2020, Plaintiffs wrote to Lupin, demanding that it produce additional launch preparation documents, manufacturing documents, launch timelines, and the final approval letter for Novel's ANDA, as well as demanding answers to their data questions raised in August 2019. (Chiorean Decl. Ex. 11.)

21. On January 24, 2020, Lupin requested that Plaintiffs meet and confer about their January 13th letter.

22. On January 29, 2020, Plaintiffs repeated their demand that Lupin produce additional launch preparation documents, final ANDA approval letters, and demanding a response to their August 2019 letter regarding Lupin's and Novel's data. A true and correct copy of the email chain reflecting this exchange is annexed hereto as **Exhibit 9**.

23. Lupin responded the same day, identifying to Plaintiffs by Bates range Novel's and Lupin's launch preparation documents that had already been produced.

24. Undeterred, Plaintiffs responded by letter dated February 3, 2020, reiterating Plaintiffs' demands for Novel manufacturing documents, Novel launch preparation documents, Lupin's and Novel's final ANDA approval letters, additional Lupin launch preparation documents, and demanding answers to Plaintiffs' data questions. Although Plaintiffs' letter

⁷ Likewise, Novel made a supplemental production of 18 documents (1,826 pages) pursuant to the same agreement. Novel's production consisted of launch preparation documents.

claims that Lupin “already committed to produce” additional launch preparation documents, Plaintiffs’ citation for this statement is our March 29, 2019 and April 19, 2019 correspondence, neither of which reflects such an agreement by Lupin. *See infra* ¶¶ 7-8. Indeed, our April 19, 2019 correspondence inquired whether Plaintiffs would agree to cost shifting as to the sought launch preparation and manufacturing documents, but Plaintiffs never responded to Lupin’s inquiry regarding cost shifting. Plaintiffs, again, conclude their February 3rd correspondence by threatening to move to compel compliance with their Subpoenas. A true and correct copy of Plaintiffs’ February 3, 2020 letter to Lupin is annexed hereto as **Exhibit 10**.

25. On February 28, 2020, Lupin made a supplemental production of 24 documents (28 pages) consisting of additional launch preparation and manufacturing documents located following a reasonable search.⁸ Our February 28th letter also addressed Plaintiffs’ outstanding questions concerning Lupin’s and Novel’s data. A true and correct copy of Lupin’s February 28, 2020 letter to Plaintiffs is annexed hereto as **Exhibit 11**.

26. Once again, Lupin met and conferred with Plaintiffs on March 10, 2020 about their evolving demands. This time, Plaintiffs requested additional launch preparation and manufacturing documents from Lupin’s facility in Goa, India. Plaintiffs also requested additional manufacturing documents from Novel, and raised additional questions about Novel documents and data.

27. Beginning on March 13, 2020, our firm’s offices were closed due to the ongoing global COVID-19 pandemic, and our attorneys began working from home. Similarly, Lupin personnel in the United States began working remotely. Lupin Ltd. personnel in India have been

⁸ At the same time, Novel made a supplemental production of 36 documents (42 pages) consisting of similar documents.

under a complete lockdown, which stymied our efforts to obtain any further information from personnel in the Goa facility.

28. On April 7, 2020, Plaintiffs wrote to Lupin demanding that it “produce the missing documents” and answer Plaintiffs’ questions about Lupin and Novel data, or provide a date certain by which Lupin would do so. Again, Plaintiffs threatened to “seek redress from the court.” A true and correct copy of Plaintiffs’ April 7, 2020 letter to Lupin is annexed hereto as **Exhibit 12**.

29. Lupin responded to Plaintiffs that same day to again confirm that Lupin was working to determine whether Lupin had any other documents responsive to the Subpoena. My colleague noted, “[h]owever, the current coronavirus pandemic has made it even more difficult for our client to address Plaintiffs’ latest series of questions, or otherwise to definitively confirm that no such documents exist.” Accordingly, Lupin noted that we would not comply with Plaintiffs’ unreasonable April 10th deadline, and that we would advise further when we had more information. A true and correct copy of Lupin’s April 7, 2020 email to Plaintiffs is annexed hereto as **Exhibit 13**.

30. Plaintiffs sent two letters dated April 10, 2020 to Lupin and Novel. As to Novel, Plaintiffs requested “an executed declaration under oath” to the extent that Novel was ultimately unable to locate any additional responsive documents. Plaintiffs further asked for confirmation that Novel had produced all relevant sales and pricing data, and answered all of Plaintiffs’ questions concerning Novel data. As to Lupin, Plaintiffs again (falsely) claimed that Lupin agreed to produce launch preparation documents in April 2019, and demanded that Lupin produce launch preparation documents “aside from forecasts.” True and correct copies of Plaintiffs’ April 10, 2020 letters to Lupin and Novel are annexed hereto as **Exhibit 14**.

31. On April 17, 2020, having located no additional responsive documents despite our ongoing reasonable search, my colleague responded to Plaintiffs on behalf of Lupin and Novel, confirming that Lupin and Novel had fully complied with Plaintiffs' Subpoenas through their rolling productions. We noted further that Lupin's production reflected that it did not have FDA approval to launch generic Exforge until March 2015. (Chiorean Decl. Ex. 3.)

32. Lupin did not hear from Plaintiffs in response to its letter until they filed this Motion to Compel on May 29, 2020. The Motion seeks production of nine categories of launch preparation and manufacturing documents from Lupin, none of which were addressed in the parties' recent correspondence or meet and confers. And as to the manufacturing documents, they remain inaccessible in Lupin's Goa facility, due to the ongoing lockdown in India.

33. On June 2, 2020, Lupin wrote to Plaintiffs to offer to meet and confer further in an effort to avoid unnecessary motion practice. A true and correct copy of Lupin's June 2, 2020 email to Plaintiffs is annexed hereto as **Exhibit 15**.

34. On June 8, 2020, Plaintiffs responded, asserting that Lupin's production was deficient because Plaintiffs were "unable to determine" eight factual issues with respect to Lupin's launch preparations and manufacturing for generic Exforge. Plaintiffs again repeated the false claim that Lupin had "already agreed" to produce all of the documents sought. A true and correct copy of Plaintiffs' June 8, 2020 email to Lupin is annexed hereto as **Exhibit 16**.

35. On June 11, 2020, Lupin produced to Plaintiffs its New Product Launch meeting minutes from January 2015 through June 2015, explaining that it was an oversight that the documents had not been included in Lupin's prior February 2020 production. A true and correct copy of the letter accompanying Lupin's June 11, 2020 production to Plaintiffs is annexed hereto as **Exhibit 17**.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct and that this document was executed in Washington, D.C.

Dated: June 12, 2020

/s/ Zarema Jaramillo
Zarema A. Jaramillo